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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/501,743	07/12/95	FAHIM	R 1038-517-MIS

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HM21/0527

EXAMINER

CAPUTA, A

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 05/27/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

08/501,743

Applicant(s)

Fahim et al.

Examiner

Anthony C. Caputa

Group Art Unit

1645

☒ Responsive to communication(s) filed on 3 Mar 1998

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 27-39 and 42 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 27-39 and 42 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1645

### **DETAILED ACTION**

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1645.

#### ***Claim Rejections - 35 USC § 112***

2. Claims 27-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 27-39 were rejected for using the phrase "a case of disease caused by infection by *B. pertussis*".

Applicants appear to argue the rejection should be withdrawn since the disease caused by *B. pertussis* is pertussis (whooping cough). Applicants argument is acknowledged. However, applicants arguments are not commensurate in scope with the claimed invention. Since the invention as recited broadly sets forth "the disease caused by infection by *B. pertussis*" it is unclear as set forth in the last Office Action if the claimed compositions are intended to protect against only pertussis or other unspecified diseases. The Examiner suggest applicants amend the claims to pertussis to obviate the rejection.

3. The prior rejection of claims 27-39 and 42 under 35 U.S.C. 112, second paragraph, for using the phrase "selected relative amounts", "about", and reciting the various components in terms of micrograms of nitrogen is withdrawn in view of applicants arguments.

#### ***Claim Rejections - 35 USC § 102***

4. The prior rejection of claims 27-29, 31-34, 38, 39, and 42 under U.S.C. 102(b) as being anticipated over Englund et al is maintained for the reasons set forth in the last Office Action.

Art Unit: 1645

Applicants assert that the rejection should be withdrawn since Englund et al. does not describe the vaccine composition having the efficacy as recited. Applicants argument is acknowledged. However, the vaccine of the prior art appears to be the same as the vaccine claimed by applicants. Accordingly, the vaccine as set forth by Englund et al. appears to be consistent with the various characteristics inherent to the vaccine as claimed (i.e. vaccine would have an efficacy of at least about 70% as specified in claim 27).

Since the Office does not have the facilities for examining and comparing applicant's vaccine with the vaccine of the prior art, the burden is on applicant to show a novel difference between the claimed composition and the composition of the prior art (i.e., that the composition of the prior art does not possess the same functional characteristics of the claimed composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicants argue the rejection should be withdrawn since the reference by Englund et al is non-enabling. Applicants specifically argue that Englund et al provide insufficient detail to prepare agglutinogens 2 and 3. Applicants arguments are not persuasive since 1) Englund et al set forth that "Agg antigens were prepared from bacteria that had been disrupted with urea, heat-treated, and purified by precipitation and chromatography" (see page 1437; Column 1); 2) Englund et al set forth that the prior art (Reference 3; Robinson et al.) has purified Aggs (see page 1436; Column 1); and 3) Englund et al discloses Agg 2 and 3 are surface antigens associated with the bacterial fimbriae (see page 1436; Column 1).

For the reasons set forth above and in the last Office Action said rejection is maintained.

5. The prior rejection of claims 27-29, 31-34, 38, 39, and 42 under U.S.C. 102(b) as being anticipated over Cherry is withdrawn upon further consideration by the Examiner.

Art Unit: 1645

***Claim Rejections - 35 USC § 103(a)***

6. The prior rejection of claims 27-39 and 42 under U.S.C. 103(a) as being unpatentable over Englund et al. is maintained for the reasons set forth in the last Office Action.

Applicants argue that Englund et al is non-enabling. Applicants argument are persuasive for the reasons set fort above (see item 4). Applicants argue that efficiency of the vaccine formulation would not have been predicted. Applicants argument is not sufficient to obviate the rejection. The mere discovery of characterizing features of a vaccine (e.g. the efficiency of the vaccine) does not impart unbviouness to the vaccine. Since the Patent Office does not have the facilities for examining and comparing applicant's vaccine with the vaccine of the prior art reference, the burden is upon applicants to show an unobvious distinction between the structural and functional characteristics of the claimed vaccine and with the vaccine of the prior art. See in re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). Mere discovery that claimed composition possesses property not disclosed for prior art does not alone defeat prima facie case of obviousness and it is not necessary, in order to establish prima facie case, to show an expectation from the prior art that claimed composition will have same or similar utility as one newly discovered by applicants. See In re Dillon, 16 USPQ2d 1897 (Fed. Cir. 1990).

7. The prior rejection of claims 27-39 and 42 under U.S.C. 103(a) as being unpatentable over Cherry is withdrawn upon further consideration by the Examiner.

***Conclusion***

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 1645


the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication should be directed to Dr. Anthony C. Caputa, whose telephone number is 703-308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is 703-308-0196.

Papers related to this application may be submitted to Art Unit 1645 by facsimile transmission. Papers should be faxed to Art Unit 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703)-308-4242.

Anthony C. Caputa, Ph.D.

26 May 1998



ANTHONY C. CAPUTA  
PRIMARY EXAMINER